REMARKS

Claims 1 and 2 are pending in this application. Claim 2 has been canceled.

Claims 1 and 2 have been rejected under 35 U.S.C. 102(b) as being anticipated by Stewart et al. It is suggested that Stewart et al. teach that there is a positive correlation between relaxin and placental function. Applicant's prior argument was not found to be persuasive.

Stewart et al. teach that levels of relaxin can be measured before and after administering oxytocin. Oxytocin is used clinically for the sole purpose of either terminating a problematic pregnancy to save the life of the mare, or to induce premature birth. It is not used as a drug treatment to maintain pregnancy or promote relaxin production. The short-term rise in plasma relaxin reported by Stewart et al. in response to oxytocin is due to purging of the hormone from the placenta. Following parturition, plasma relaxin levels decline rapidly as a consequence of the delivery of the placenta, a natural function of giving birth.

Stewart et al. further teach that relaxin levels during gestation are highly variable between equine species(p. 651,

column II, paragraph 2),and that each species has a different pattern of relaxin levels at different times of the pregnancy (p. 650, column I, paragraph 3 through column II, paragraph 1). It is also taught that it is essential to know the normal relaxin levels for each species (p. 652, column I, paragraph 1). Stewart et al. acknowledge that more studies, with a larger population of mares are needed to "determine if relaxin concentrations are predictive of an adverse pregnancy outcome" (p. 652, col. I, lines 1-5).

MPEP 2131 states that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". Stewart et al. do not teach or suggest methods to use plasma relaxin levels to predict troubled births.

In contrast to Stewart et al., the present invention teaches a method for predicting treatment efficacy in pregnant mares, comprising measuring relaxin levels before and after administering a drug or treatment to an animal believed to be at risk for a problematic pregnancy or birth. The drug or treatment of the present invention must <u>stimulate</u> and/or <u>restore</u> elevated plasma relaxin levels to be effective. Failure to increase

circulating relaxin levels is predictive of the lack of efficacy of the drug treatment in preventing preterm delivery in the mare. (Specification p. 9, lines 29-31). It is further taught that equine relaxin can be administered to supplement and alleviate a placental insufficiency of plasma relaxin levels based upon a problem pregnancy in accordance with the method of the present invention. (Specification, p. 10, lines 5-7).

Clearly, the present invention is not anticipated by Stewart el al. Although the prior art has recognized a correlation between plasma relaxin levels and an adverse pregnancy outcome, there is no teaching or suggestion of how to use plasma relaxin levels to determine drug or treatment efficacy in mares, as claimed in the present invention. Nor, do the teachings of Stewart et al. provide each of steps a-c of claim 1, as required by MPEP 2131.

In the instant claims, the method of the present invention concerns predicting efficacy of treatment of a disease or condition that alters placental function. Oxytocin, the drug administered in the prior art reference, is a drug that is not used to treat a disease or condition that alters placental function. Oxytocin is not administered to the animals in the

study of Stewart et al. in order to treat any disease or condition but merely as a method to induce a normal foaling.

Further, Applicants respectfully disagree with some of the Examiner's analysis and conclusions. For example, at page 2 (Section 3, paragraph II) of the Office Action, the Examiner suggests that both burros and thoroughbred mares were stimulated to deliver with oxytocin. Stewart et al. teach that only burros were stimulated with oxytocin (Materials and Methods, p. 649, column I, and Results, Figure 2). The Examiner further suggests that the prior art reference teaches that a "sensitivity to oxytocin develops late in gestation, and mares induced to abort in midpregnancy did not show a rise in relaxin". Applicants respectfully point out that none of the mares were "induced" to abort in midpregnancy. The only animals given a drug in Stewart's studies were burros. The aborting standardbred mares, in which low levels of relaxin were measured, were not given oxytocin.

Accordingly, reconsideration and withdrawal of this Rejection is respectfully requested.

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